Effects of postprandial hyperglycemia on aortic elasticity in impaired glucose tolerance and diabetes mellitus type 2

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON34650

Source
ToetsingOnline

Brief title
Postprandial hyperglycemia and aortic elasticity

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
elasticity aorta; pulse wave velocity

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Center for Translational Molecular Medicine

(CTMM; www.ctmm.nl);project PREDICCt (grant 01C-104)

Intervention

Keyword: impaired glucose tolerance, MRI, oral glucose tolerance test, pulse wave velocity

Outcome measures

Primary outcome

Pulse Wave Velocity

Secondary outcome

Heart Rate variability

Glucose and insulin levels

Cardiac function

Study description

Background summary

Type 2 diabetes mellitus (T2DM) is associated with high mortality and morbidity due to cardiovascular complications.
The pulse wave velocity (PWV) is a measure of arterial elasticity. An increase in arterial stiffness is associated with an increased cardiovascular risk and even an independent predictor of mortality in patients with T2DM. The PWV can be measured by use of velocity encoded magnetic resonance imaging (MRI).
Insulin resistance and hyperglycemia are involved in different processes leading to endothelial dysfunction.
In patients with T2DM chronic hyperglycemia is involved in the formation of advanced glycation products (AGEs), which can also increase arterial stiffness.

Study objective

We aim to study the short-term effects of postprandial hyperglycemia in patients with impaired fasting glucose and in patients with T2DM on aortic stiffness as measured by PWV.
Secondly, we study the effects of postprandial hyperglycemia on the sympathetic activity in those subjects.

Study design

Random assignment, placebo-controlled, cross-over design with 2 study days separated by 7-day intervals.

Intervention

Oral glucose tolerance test

Study burden and risks

Three visits, including screening are applicable to all subjects. At screening and during the MRI scan blood samples will be taken via venous puncture or iv cannula. There are no inherent hazards from MRI when MR exclusion criteria have been checked. During the MRI scan patients have to lie still inside the small bore of the MRI machine. This may cause some discomfort. This will be as much possible alleviated by the possibility of playing music CD*s brought by the patients themselves. During changing of surface coils, patients can move freely, and can visit the restroom if needed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

For all: Age: 18-65 years, informed consent.
Patients with T2DM: untreated or treated with oral glucose lowering agents
HbA1c < 8.5%
Subjects with impaired fasting glucose: fasting glucose 5.6-6.9 mmol/l

Exclusion criteria

Healthy controls and impaired glucose tolerance: grade 2 or 3 hypertension at screening (ESC guidelines); use of glucose lowering mediaction/ statins or antihypertensives; any significant chronic disease; smoking; contra-indications MRI
Patients with type 2 diabetes: tension: >140/90 mmHg; use of insulin/ thiazolidinediones/ smoking/ contra-indications MRI

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-05-2010

Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL30975.058.09